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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

DRODGE, JOSEPH W

ART UNIT PAPER NUMBER

1723

DATE MAILED: 10/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/635,795

Applicant(s)

CROWE ET AL.

Examiner

Joseph W. Drodge

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

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The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-66 of copending Application No. 10/635,396 in view of Wolkers et al publication "Human Platelets Loaded with Trehalose Survive Freeze-Drying. The instant claims substantially differ from the claims of '396, in adding the limitation of the disposing being at a temperature of about 25 degrees C or greater. However, Wolkers et al teach that blood cells optimize uptake of trehalose at temperatures about 37 degrees. It would have been obvious to the ordinarily skilled artisan to have practiced the method defined in the '396 claims while operating at a temperature of greater than 25 degrees C, as taught by Wolkers et al to optimize cell uptake.

This is a provisional obviousness-type double patenting rejection.

Claims 21-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1,9 and 10 of copending Application No. 10/635,754. Although the conflicting claims are not identical,

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they are not patentably distinct from each other because instant claims are genus to the species claims of '754, differing only in being silent as to specific quantity of hemolysis, specific types of salts and specific types of buffers in the solution; if necessary, the salts and buffers recited in the '754 claims are conventional.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-17 are rejected under 35 U.S.C. 102(e) as being anticipated by McHale patent 6,495,351. McHale discloses loading agents in the form of solutes from solutions into red blood cells (erthrocytes) using a combination of hypo- or hypo- osmotic pressure, osmotic shock, osmotic pulsing, dialysis and endocytosis (see especially column 6, line 49-column 7, line 2 and column 14, lines 41-43.

With regard to claims 2,6-11 and 14, solute concentrations and gradients are maintained and optimizing loading efficiencies are discussed at column 7, lines 52-54, column 9, lines 17-22, column 15, lines 32-35 and column 23, lines 48-51.

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With regard to claims 9 and 10, the solute loaded may comprise an oligosaccharide as column 7, lines 64-67 teach agents optionally being in oligomer form and column 7, line 43 and column 19, lines 22-25 teach loading of glucose.

Claims 18-20 and 27-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Crowe et al PG PUBS Document US2002/0076445, published 6/20/2002. Crowe et al '445 disclose preparation and use of a composition for preserving red blood cells and its use in lyophilization/freeze drying followed by reconstituting in a reconstituting solution with composition comprising drying salt solution, solute, inert substance and protein (see in particular paragraphs 105 and 114-124). Rehydration is disclosed at paragraph 85, etc. Regarding claims 19,20 and 28-32, these paragraphs also disclose the recited concentration of solute, salt solution, inert substance and protein, see especially paragraph 114 that states that concentrations or mixing proportions are not limited by the Examples given in the text.

Claims 21-23 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Meryman et al patent 5,250,303.

Meryman et al disclose reducing hemolysis in cells during storage/incubation "many-fold", and to less than 10% (column 9, line 59-column 10, line 4, column 12, lines 17-18 and 57-68 etc.) by a loading solution that comprises at least a solute of at least 200mM (column 10, lines 5-19 and column 15, lines 20-27), and optionally also a salt (column 7, lines 53-62). For claims 22 and 33, Table 2 at column 8, lists inert substances, starches and proteins contained in the loading solutions. For claim 23, washing and drying are disclosed at column 7, lines 26-44 and column 11, lines 26-34.

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Claims 24-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Goodrich et al patent 5,045,446.

Goodrich et al disclose stabilizing cells, including loading cells in a loading solution to maintain high levels of oxyhemoglobin, i.e. corpuscular hemoglobin, by use of solutes such as PVP (see especially Example Two), levels of at least 50mM salt in the solution are also disclosed as required by claim 26 (column 4, lines 24-30 and column 5, lines 19-24).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beattie et al patent 5,827,741 in view of McHale patent 6,495,351 and the publication to Wolkers et al. With regard to independent claims 1,14,31 and 39, Beattie et al disclose loading of trehalose solute into blood cells such as platelets from solutions containing high concentrations of trehalose by utilizing concentration gradients (see the Abstract, column 3, lines 39-64, column 5, lines 48-57 and column 6, lines 35-43).

The claims differ in requiring that the loading be by the mechanism of hyperosmotic pressure or intracellular osmolarity. However, McHale teaches to load a wide variety of agents into red blood cells and other blood cells by mechanisms including numerous forms of osmosis and osmolarity including hypo or hyperosmolarity, concentration gradients, osmotic shock, osmosis, dialysis and endocytosis (especially column 6, lines 59-67); while Wolkers et al teach at page 86 to load trehalose into blood platelet cells by endocytosis.

Hence, it would have been obvious to one of ordinary skill in the art to have augmented the Beattie et al method by using hyperosmotic pressure or intracellular osmolarity forces to load the agents, since McHale and Wolkers et al teach that such forms of loading agents into blood cells transfer agents rapidly into the cells and without damaging the cells.

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Regarding claims 2,6-11 and 14, Beattie at column 3, lines 54-64 disclose, in considerable detail a wide range of possible trehalose agent concentrations and hence concentration gradients across the cells that range from 10 mM to 15 M and also see column 4, lines 15-16 of Beattie et al regarding "concentration of trehalose in the solution not being critical and column 4, lines 31-34 concerning avoiding of eliminating a concentration gradient that would cause outward osmosis or diffusion out of the cell.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Goodrich et al patent 5,043,261 is related to Goodrich '446.



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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Drodge at telephone number 571-272-1140. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached at 571-272-1151. The fax phone number for the examining group where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either private PAIR or Public PAIR, and through Private PAIR only for unpublished applications. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JWD

October 17, 2005

  
**JOSEPH DRODGE**  
**PRIMARY EXAMINER**